

APR 13 2005
Customer No.: 07278

04-15-05
Docket No.: 04266/100M192-US4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Amedeo LEONARDI, et al.

Serial No.: 10/688,061

Art Unit: 1626

Filed: October 16, 2003

Examiner: TBA

For: **LISINOPRIL/LERCANIDIPINE COMBINATION THERAPY**

April 13, 2005

INFORMATION DISCLOSURE STATEMENT

MAILSTOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
(Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.).

- ☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent(s) and Patent Publication(s) on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these

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documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP § 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) CD and CF can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

☐ 5. Other information being provided for the examiner's consideration follows: An International Search Report, dated _____, which issued during the prosecution of International Application No. _____ which is a counterpart to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

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CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Application(s):

(1) U.S. Patent Application Serial No. 10/835,095, filed April 28, 2004.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mitchell Bernstein", written over a horizontal line.

Mitchell Bernstein, Ph.D.

Registration No. 46,550

Agent for Applicants

April 13, 2005

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Application No. (if known): 10/688,061

Attorney Docket No.: 04266/100M192-US4

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Information Disclosure Statement (4 pages)
Form PTO/SB/08a/b (1 page) and 6 References
Return Receipt Postcard



PTO/SB/08a/b (08-03)

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/688,061
				Filing Date	October 16, 2003
				First Named Inventor	Amedeo Leonardi
				Art Unit	1626
Examiner Name	TBA				
Attorney Docket Number	04266/100M192-US4				
Sheet	1	of	1		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A	6,852,737	02/08/2005	Bonifacio, et al.	
	B	6,162,802	12/19/2000	Papa, et al.	
	C	6,086,919	07/11/2000	Bauer, et al.	
	D	2003/0069285	04/10/2003	Amedeo, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
	1	WO 03/097067	11/27/2003	Novartis AG		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	2	Epstein, MD, Murray (2001), "Lercanidipine - A Novel Dihydropyridine Calcium-Channel Blocker," <i>Heart Disease</i> 3: 398-407	
	3	Martell, N. (2003) "Association of Lercanidipine Plus Enalapril to Control Blood Pressure," presented at the American Society of Hypertension, May 14-17, 2003, New York, NY (Abstract)	
	4	Messerli, MD, Franz (2002), "Vasodilatory Edema: A Common Side Effect of Antihypertensive Therapy," <i>Current Cardiology Reports</i> 4: 479-482	
	5	Morgan, Trefor et al. (2002), "A Comparison of Candesartan, Felodipine, and Their Combination in the Treatment of Elderly Patients with Systolic Hypertension," <i>American Journal of Hypertension</i> 15(6): 544-549	
	6	Ruzicka, MD, Marcel et al. (2002), "Combination therapy as first-line treatment of arterial hypertension," <i>Can. J. Cardiol.</i> 18(12): 1317-1327	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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